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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,019	09/10/1999	AKIRA KOMORIYA	3273.002US1	3625

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/394,019

Applicant(s)

KOMORIYA ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed April 12, 2004 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1-15 are pending.

Applicant's amendment filed April 12, 2004 is acknowledged, and applicants' response has been fully considered. Claims 1, 4, 6, 9 and 12 have been amended. Therefore, claims 1-15 and SEQ ID NOs:212 and 248 are examined.

Drawings

3. Nine pages of formal drawings filed April 12, 2004 are acknowledged.

Sequence Listing

4. A paper copy and a computer readable format (CRF) of sequence listing filed April 12, 2004 are acknowledged, and CRF has been entered. Tables 3 and 4 which have been amended to cite amino acid sequences presented with one letter code are acknowledged.

Rejection Withdrawn

Claim Rejections-Obviousness Type Double Patenting

5. The previous rejection of claims 1-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5-13 of U. S. Patent 6,037,137, is withdrawn in view of a terminal disclaimer filed April 12, 2004, and applicant's response at page 16 in the amendment filed April 12, 2004.

Claim Rejections - 35 USC § 112

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6. The previous rejection of claims 1-15, under 35 U.S.C.112, second paragraph, regarding the term "Nlu" and SEQ ID NO:248 for not conforming the formula of claim 1, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 16 in the amendment filed April 12, 2004.

Claim Objections

7. Claim 1 is objected to because the amended formula: $F^1-aa^1_j(S^1)_i-aa^2-aa^3_k-aa^4_l-aa^5-X_m-P-Y_n-aa^6-aa^7_o-(aa^8-aa^9)_p-aa^{10}_q(S^2)_r-F^2$ is not indicated in the specification. The amended formula of claim 1 is supported by the description of Formula V (pages 18-19 of the specification) and by the peptide sequences of Tables 3 and 4, where aa^2-aa^3 is always shown as a single amino acid or two amino acids, as indicated in the applicant's response (page 16), and, thus the amended formula is not a new matter. However, it is different from the Formula V ($F_1-aa^1_j(S^1)_i-(aa^2-aa^3)_k-aa^4_l-aa^5-X_m-P-Y_n-aa^6-aa^7_o-(aa^8-aa^9)_p-aa^{10}_q(S^2)_r-F_2$, page 18, line 15), applicant should amend Formula V to be consistent with the formula of claim 1.

8. Claim 9 is objected to because the claim recites 9-(2,5 (or 2,6)-dicarboxyphenyl)-3,6-bis(dimethylamino)xanthylumhalide, 9-(2,5 (or 2,6)-dicarboxyphenyl)-3,6-bisamino-xanthylum halide, 9-(2,5)-dicarboxyphenyl)-2,7-dimethyl-3,6-bis(ethylamino)xanthylum halide, and 9-(2,6)-dicarboxyphenyl)-2,7-dimethyl-3,6-bis(ethylamino)xanthylum halide. The first two fluorophores contain either 2,5-dicarboxyphenyl isomer or 2,6-dicarboxyphenyl isomer, which should be cited separately since they are two different groups, e.g., the first compound should be cited as 9-(2,5-dicarboxyphenyl)-3,6-bis(dimethylamino)xanthylum halide and 9-(2,6-dicarboxyphenyl)-3,6-bis(dimethylamino)xanthylum halide. The last two fluorophores

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should be indicated as 9-(2,5-dicarboxyphenyl) or 9-(2,6-dicarboxyphenyl) in the group instead of 9-(2,5)-dicarboxyphenyl) or 9-(2,6)-dicarboxyphenyl) which contains an extra parenthesis.

10. Claim 12 is objected to because of misspelling or incorrect formula of “4,4=-dimethoxy”, “4,4-dimentyl” or “2,6-diaxocyclohexylidene” in the term “4,4=-dimethoxybenzhydryl (Mbh)” or “1-(4,4-dimentyl-2,6-diaxocycloheylidene)ethyl (Dde)”.

The term Mbh or Dde reads as a group having a right chemical name.

Objection to New Matter Added to Specification

11. The amendments filed March 17, 2003 and April 12, 2004 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification does not indicate C7 as an X or Y group in the formula of fluorogenic peptides (see page 19, lines 2-9), however, the amended claim 1 recites the new matters.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-15 are directed to a fluorogenic composition having the formula $F^1-aa^1_j(S^1)_i-aa^2-aa^3_k-aa^4_l-aa^5-X_m-P-Y_n-aa^6-aa^7_o-(aa^8-aa^9)_p-aa^{10}_q(S^2)_r-F^2$, where X and Y is Gly, β Ala, γ Abu, Gly-Gly, Ahx, C7,.....Ahx-Ahx-Gly. However, the specification indicates a fluorogenic composition having the formula V, where X and Y is Gly, β Ala, γ Abu, Gly-Gly, Ahx,.....Ahx-Ahx-Gly (page 18, line 5-page 19, line 9), it does not indicate X or Y group is C7. Furthermore, the specification has not defined the term C7. Without guidance on the structural identity of C7, one skilled in the art would not know what the fluorogenic peptide containing C7 is, and whether the peptide can be used for the detection of the protease activity. The lack of a structural description of C7 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 are indefinite because the claim recites "C7" as an X or Y group, it is not clear what structure the C7 has since neither the specification nor the claim define the

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term. Claims 2-15 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner



June 24, 2004